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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,412	03/25/2004	Kaoru Asano	11333/35	8939
757 7590 04/09/2009 BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			EXAMINER TOTH, KAREN E	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 04/09/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/810,412

Applicant(s)

ASANO ET AL.

Examiner

KAREN E. TOTH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-9,11-24,26-28,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-9,11-24,26-28,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

2. Claims 1, 3, 4, 7-9, 11-24, 26-28, 37, and 38 are rejected under 35 U.S.C. 101 because the claimed inventions are directed to non-statutory subject matter.

Claim 1, in line 11, recites the limitation "has a contact area with the skin". The human body may not be claimed. For the purposes of examination, the claim will be treated as though reading --is configured to contact the skin over an area--.

Claim 8, in line 12, recites the limitation "has a contact area with the skin". The human body may not be claimed. For the purposes of examination, the claim will be treated as though reading --is configured to contact the skin over an area--.

Claim 9 recites the limitation "the contact area of the second collection material and the skin is". The human body may not be claimed. For the purposes of examination the claim will be treated as though reading --the second collection material is configured to contact the skin over a contact area of--.

Claim 19, in line 15, recites the limitation "has a contact area with the skin". The human body may not be claimed. For the purposes of examination, the claim will be treated as though reading --is configured to contact the skin over an area--.

Claim 24, in line 11, recites the limitation "has a contact area with the skin". The human body may not be claimed. For the purposes of examination, the claim will be treated as though reading --is configured to contact the skin over an area--.

Claim 26, in line 9, recites the limitation "has a contact area with the skin". The human body may not be claimed. For the purposes of examination, the claim will be treated as though reading --is configured to contact the skin over an area--.

Claim 37, in line 9, recites the limitation "has a contact area with the skin". The human body may not be claimed. For the purposes of examination, the claim will be treated as though reading --is configured to contact the skin over an area--.

Claim 38, in line 3, recites the limitation "has a contact area with the skin". The human body may not be claimed. For the purposes of examination, the claim will be treated as though reading --is configured to contact the skin over an area--.

Claim Rejections - 35 USC § 103

3. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn (US 6438414).

Regarding claim 37, Conn discloses a method comprising forming analyte transmission paths in skin (column 8 line 60 to column 9 line 7); placing a through-current electrode part and a first electrode part on skin in the location where the analyte transmission paths have already been formed, since the transmission enhancing techniques, such as pricking, would take place prior to application of electrodes (column 15, lines 24-34; column 18, lines 4-6); applying electrical energy to the electrode parts (column 15, lines 27-34); and extracting analyte at the first electrode part (column 15, lines 34-36), where the first extraction electrode part may have a contact area with the skin of less than 25 mm² (column 18, lines 4-6) – Conn defines the "biosensor" as

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comprising an electrode (column 9, lines 48-55), so creating a biosensor having a contact area of 10 mm^2 inherently means the electrode's area is no greater than 10 mm^2 .

Regarding claim 38, Conn discloses a device comprising a first electrode part (elements 4, 8 and 12) having a contact area of between about $0.01\text{-}25 \text{ mm}^2$ (column 18, lines 4-6); a second electrode part (element 14); and a component to supply power to the first and second electrodes in order to extract an analyte (column 15, lines 24-36). Conn defines the system's "biosensor" as comprising an electrode (column 9, lines 48-55), so creating a biosensor having a contact area of 10 mm^2 inherently means the electrode's area is no greater than 10 mm^2 .

Allowable Subject Matter

4. Claims 1, 3, 4, 7-9, 11-24, and 26-28 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 101 set forth in this Office action.

The prior art of record fails to anticipate or make obvious the inventions of claims 1, 3, 4, 7-9, 11-18, 24, and 26-28 including, *inter-alia*, extracting an analyte using a device comprising, among other features, an electrode with a collection material that is configured to contact the skin of a user over a contact area of between 0.01 and 25 mm^2 .

The prior art of record fails to anticipate or make obvious the inventions of claims 19-23, including, *inter-alia*, extracting an analyte using a device comprising, among other features, a plurality of electrodes, one of which is used to form a path and

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comprises a chamber containing purified water and ion-conductive material, where the chamber is configured to contact a user's skin over a contact area of less than 25 mm².

Response to Arguments

5. Applicant's arguments with respect to claims 1, 3, 4, 7-9, 11-24, 26-28, 37, and 38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735